QUARTER REPORT
ON INTERIM PERIOD OF THE PROJECT

" Case-control Study of Leukemia among Chornobyl clean-up Workers in Ukraine "

(time period from 1.04.2000 to 30.06.2000)

Task 1.
Choice of the personnel for groups at RCRM
(administrative group)

According to the schedule for the interim period and Phase II the personnel was chosen for groups at RCRM. The duties of each person were specified according to the tasks and the working hours percent needed for accomplishing each tasks was estimated.

Task 2.
Meetings with administration and medical representatives of the oblasts.
(administrative, epidemiologic and hematologic groups)

During this period repeated meetings with administration and medical representatives of Dnipropetrovsk, Kharkiv, Cherkasy, Chernihiv, Kyiv oblasts and Kyiv city were held. The reports are given in Appendix 1.

Task 3.
Organize groups for accomplishing study in each oblast
(administrative, epidemiologic and hematologic groups)

The personnel has been chosen for work in Cherkasy, Chernihiv, Kyiv, Dnipropetrovsk, Kharkiv oblasts and Kyiv city. They were instructed as to the main tasks of the Project and scope of the work to be accomplished in each oblast.

Tasks 6-7.
Draw up a plan of the Operation Manual
(administrative, epidemiologic and hematologic groups)

According to the schedule a detailed plan of the Operation Manual was drawn up. Detailed description of the Operation Manual is given in Appendix 2.

Task 17.
Check up the Cohort File to reveal duplicates.
(epidemiologic group)

A program was designed making it possible to reveal the entries concerning one person i.e. duplicates, the family name, name, patronymic and date of birth being entirely identical.

Thus, 4,492 entries were revealed to be inquired as to their withdrawal from the Cohort file.

Distribution of such entries according to the regions of residence is presented in Table 1.

Table 1.

Distribution of the entries according to the regions of residence.

Oblast and its code	Total number of the entries encountered several times
Dnipropetrovsk(4)	1429
Kyiv 10)	59
Kharkiv(20)	703
Cherkasy(23)	302
Chernihiv(25)	223
Kyiv city(26)	1776
Total	**4492**

Part of the information was checked up with the help of the employees of the oblast Registry. As a result, 1,275 entries were withdrawn from the duplicates revealed.

Task 18.
Evaluate completeness of the information on the medical follow-up of the persons involved in the Cohort using computer data of the State Registry for the oblasts under study.
(epidemiologic group)

The persons from the Cohort file were chosen according to the following principles:

- no data as to the death;
- no data as to the last medical examination (1998).

Distribution of such persons as to the regions of residence and period during which the data are not available is presented in Table 2.

Table 2.

Distribution of the persons according to the regions of residence and period during which the data are not available.

Oblast of residence	Data available for 1998	Years for which the data are not available					
		1998	1997-1998	1996-1998	1995-1998	1994-1998	1993-1998
Dnipropetrovsk	13921	1044	1147	449	484	235	552
Kyiv	7610	30	73	58	9	-	46
Kharkiv	12739	781	424	462	349	203	493
Cherkasy	9916	981	351	112	55	35	77
Chernihiv	8540	1383	518	353	278	229	385
Kyiv city	24956	1623	763	1174	706	2026	2894
Total	77682	5842	3284	2608	1880	2728	4447

The corrected files were obtained from Dnipropetrovsk, Cherkasy and Chernihiv oblasts in 2000. These data are presented in Table 3. The files are in the exchange catalogue LEDO-CORREC99 on TORNADO server.

Table 3.

Reception, control, filing and processing of the correction data on the persons suffered following the Chernobyl accident and involved in the Cohort of the joint Ukrainian-American Protocol

Region		Number of the correction entries obtained	Number of the correction entries involved in the cohort
Code	Oblast		
04	Dnipropetrovsk	1091	633
23	Cherkasy	1052	285
25	Chernihiv	2630	1608

In April-May, 2000 the work was carried out as to reception, filing and registering data, data as to the dispensary examinations for 1988-1999 and dosimetry data on the persons

suffered as a result of the Chornobyl accident and involved in the departmental Registry of the Ministry of Internal Affairs.

According to this Registry the information was as follows:

- registration data on the alive persons -28,893 entries;
- data as to the dispensary examinations in 1988-1999 on the alive persons – 258, 722;
- dosimetry data on the alive persons – 18,122;
- registration data on the dead persons – 867;
- data as to the dispensary examinations in 1988-1999 on the dead persons – 5,962 entries;
- dosimetry data on the dead persons –652 entries.

From among 29,757 sufferers registered in the State Registry of Ukraine and involved in the departmental registry of the Ministry of Internal Affairs 23,376 persons are clean-up workers (including 839 dead ones). Structure of the files of the database of the Ministry of Internal Affairs of Ukraine was determined on the paper media with the name of the files fields and their characteristics.

The number of the registered sufferers in the Cohort oblasts is given in Table 4.

Table 4.

The number of the sufferers in the Cohort oblasts registered in the departmental registry of the Ministry of Internal Affairs of Ukraine.

Region		The number of entries of the registers in the Cohort oblasts	
Code	**Oblast**	**alive**	**Dead**
04	Dnipropetrovsk	1229	63
10	Kyiv	2981	79
20	Kharkiv	1087	27
23	Cherkasy	901	31
25	Chernihiv	305	12
26	Kyiv city	3529	169
Total		**10032**	**381**

On the whole, in this registry 10,413 persons were registered that may be involved in the Cohort.

Task 24.
Make up a list of the establishments the data of which will be employed to form the Leukemia Registry in each oblast.
(epidemiologic and hematologic groups).

Upon carrying out the field work in the oblasts involved in the Project to reveal the information sources as to leukemia cases and related diseases a list of establishments possessing such information was made. Detailed description of these establishments is presented in the reports of the oblasts (Appendix 1).

Task 28.
Make up a list of the cases of leukemia/related diseases at the local medical institutions (hematologic and epidemiologic groups).

To form the Leukemia Registry general principles of the instructions for the local personnel were formulated; they are presented in Appendix 3.

Task 37-41.
(dosimetric group)

EPR:

1. All doses to be reconstructed within the framework of the work on intercalibrating jointly with the Center of Applied Dosimetry, Utah University have been estimated. The Table of the doses reconstructed separately for the tongue and cheek teeth will be sent to IAEA.

2. Within the framework of the study on the X-ray procedures effect the test teeth were collected in the persons who were not clean-up workers and were 18 or more years old. 72 samples were collected involving 25 from Poltava and 47 from Kyiv oblasts. A work is in progress to prepare the teeth for dose reconstruction.

3. Information was acquired on the feasible kinds of X-ray procedures and apparatuses used in stomatology. It is anticipated to prepare a literature review on the kinds of the X-ray procedures and apparatuses used in stomatology.

4. The Bank of biosamples is being costantle replenished with the teeth collected in the clean-up workers from the oblasts involved in the Project. 85 teeth were obtained during the reported period involving 71-from Kyiv city and oblast and 14 from Dnipropetrovsk oblast.

SEAD.

1. Dr. V.P.Kruchkov modified the method as follows:

a) there is a feasibility to change weight coefficients for all factors used to estimate doses;

b) using the new method it is possible to determine factors allowing for the time spent by a clean-up worker in different places of the emergency zone. A report on the modifications above was presented at the meeting of the International dosimetric group in Lyon.

2. Doses presented in 89 clean-up workers' questionnaires were re-estimated using the modified method and compared repeatedly with EPR dosed As it is seen from the comparison the modifications suggested insignificantly improved correlation coefficients and

slope of the straight line of correlation for all groups under study involving "partisans", those who served in the 30-km zone and early clean-up workers.

MARD.

1. Dr. V.P.Kryuchkov got practically all data on the radiation situation in 30-km zone, on the industrial site and in the premises. It is anticipated to present the information in the form of databases. For the places where the data are not available it is anticipated to employ the interpolation model developed.

2. The representatives of the International dosimetric group V.P Kryuchkov and E.Matseiko met with the experts S.V Illichov, V.I.Glebov and O.S.Tsikalo participating in dose reconstruction using ADR method. A plan was discussed of the working meeting with participation of the international experts L Anspo and F.Hubert. The meeting to be held in Kyiv in July will be devoted to employment of the databases on radiation situation, on some standard episodes; on the organizations taking part in clean-up work; formulation of the rules for experts while reconstructing ADR doses.

ORD.

Within the framework of the search for additional dosimetric information we started the anticipated mail interviewing of the clean-up workers for which the doses are not available in the State Registry of Ukraine.

1. With the help of the epidemiologic groups the list of 400 clean-up workers was made including 200 persons from Kyiv city (supposedly those who served in the 30-km zone) and 200 from the oblasts selected for the study (supposedly, "partisans").

2. The draft is compiled of the questionnaire and the explanatory note to be sent by mail.

3. The letters are being dispatched. Some time later it is anticipated to send the letters repeatedly at the addresses the answers from which are not available.

Task 42.

Performing FISH analysis for high dose liquidators.

(dosimetryc group)

According to the working plan, the venous blood samples from 15 liquidators with different absorbed doses of gamma irradiation (above 30 cGy) have been received and the culturing of peripheral blood lymphocytes from these persons have been established. The frozen fixed cells from 15 persons have been stored under the temperature - 20° C. The slides from 10 persons have been prepared and treated for FISH analysis.

The FISH cytogenetic analysis of 10 liquidators had been fulfilled. For dose reconstruction only the frequency of reciprocal translocations had been used according to J. Lucas algoritm for gamma radiation exposure.

The data received are presented in the table 5.

Table 5.

The results of FISH analysis

#	Code	ODR (Gy)	Metaphase scored	Translocations		Other	Total	Dose (Gy)
				Com	Incom			
1	5.03.07	**0,35**	1000	3,00	2,00	1,00	6,00	**0,27**
2	1.28.04	**3,40**	550	57,00	9,00	2,00	68,00	**2,11**
3	6.11.02	**0,60**	1000	24,00	35,00	2,00	61,00	**0,91**
4	2_03.07	**1,56**	1000	7,00	1,00	1,00	9,00	***0,52***
5	3.04.02	**0,50**	1000	5,00	3,00	1,00	9,00	**0,36**
6	5.11.02	**1,80**	1015	59,00	9,00	5,00	73,00	**1,52**
7	2_19.11	***3,90***	500	70,00	14,00	3,00	87,00	***2,49***
8	4.11.02	**5,50**	432	148,00	31,00	18,00	197,00	**4,04**
9	1_10.02	***1,60***	1000	59,00	10,00	4,00	73,00	***1,54***
10	2.04.02	**1,20**	1000	5,00	0,00	1,00	6,00	**0,36**

All persons examined differed essentially at the degree of radioinduced cytogenetic effect (the frequency of stable chromosome aberrations, namely chromosome translocations) which depended on the absorbed radiation doses.

The data received in the second quarter of the interim period showed that in two from ten liquidators (## 4, 10) investigated with the help of FISH method biological doses (0.52 and 0.36 Gy respectively) were much lower than ODR (1.56 and 1.20 Gy respectively), so these persons cann't be include in the true high-dose group (above 1 Gy).

In person # 3 FISH dose (0.91 Gy) was higher than ODR (0.60 Gy).

In persons ## 1, 5, 6, 9 FISH doses were a little lower than ODR, but both types of dosimetry were very closed to each other (0.27 - 0.35 Gy; 0.36 – 0.50 Gy; 1.52– 1.80 Gy; 1.54 - 1.60 Gy respectively).

In cases ## 2, 7, 8 with very high ODR (more than 3 Gy) FISH doses were lower than ODR doses (2.11 - 3.40 Gy; 2.49 - 3.90 Gy; 4.04 - 5.50 Gy) but all in the range of true high doses.

Thus, the data received during two quarters of the interim period showed that in 5 from 15 persons biological doses differed significantly from ODR (in 4 cases ODR doses were

overestimated, in one case - underestimated). So, FISH technique can be use for the verification of ODR and selection of true high-dose liquidators group.

APPENDIX 1.

REPORT ON MISSION TO CHERKASY # 1.

According to the developed plan for the interim period of the Project « Proposal for Case-Control Study of Leukemia among Chornobyl Clean-Up Workers in Ukraine» a group of the Program partipants from the RCRM of the AMS of Ukraine including deputy director of the Project Volodymir G. Bebeshko, scientific secretary, hematologist Irina S.Dyagil, leader of the hematological group Victor I.Klymenko, director of the National Registry of Ukraine Gennadyi I.Kortushin and epidemiologist Natalia Gudzenko visited Cherkasy on March, 1, 2000.

The main tasks of the mission were as follows:

1. To present the Project on Phase II of the study in the oblast health department , oblast oncological dispensary , oblast department of the National Registry;

2. To specify potential information sources containing data on leukemia cases and related disorders;

3. To select responsible persons from local personnel for work with the information sources;

4. To get acquaint the local personnel involved in accomplishment of the Project in Cherkasy oblast with the aims and tasks of the work.

In Cherkasy the group from RCRM was accepted by the head of the oblast Health department of Cherkasy oblast Anatolyi P. Sytnik. Volodymir G.Bebeshko acquainted him with the main tasks of the Project; he emphasized the singnicance of the joint American-Ukrainian treaty between the National Cancer Institute of the USA and RCRM of the AMS of Ukraine to specify the role of the ionizing radiation on leukemias development; he elucidated the scope of the studies to be performed by the local personnel Anatolyi P.Sytnik supported the idea on accomplishing the Project in Cherkasy oblast within the framework of the international Program and pointed out that such level of cooperation would enable the oblast health department to achieve a qualitatively new stage.

The same issues were dealt with in the conversation with the head physician of the oblast oncological dispensary Victor V.Paramonov.

Besides, sources of information were determined on the leukemia cases registered in the oblast. They involve records of the casualty words and hematologic department of the oblast oncodispensary where all patients are registered and there is an archive of medical records. The records include data on the patient to be treated such as surname, first name and patronymic; year of birth, gender, address, the initial and final diagnoses. It was found out that there are all records available starting from 1987 up to the present. There are no losses.

Since the main bulk of information on leukemia in Cherkasy oblast is available in the oblast oncodispensary three people involving a coordinator, a hematologist and a technician were selected to be enrolled to the staff to accomplish the tasks set forth. They were instructed on the procedure of filling out the forms for the each leukemia case. The department being equipped with computers the file with the form to be filled out was provided. It was agreed that the lists with information on all leukemia cases in Cherkasy oblast would be transferred by E-mail to Kyiv for all the data to be checked.

The hematological department (head of department is Galina V.Pilipenko) is staffed with highly qualified personnel and provides diagnostics and treatment of patients with leukemia and lymphoma on the up-to-date level. All clinical information is available in the medical records in the archive of the oblast oncodispensary.

Highly qualified laboratory assistants perform laboratory work of the dispensary. The diagnostic methods are adequate and up-to-date. The biological materials are properly stored starting from 1992. The slides are available in the archive for all patients with leukemia involving clean-up workers.

Thus as a result of the field work mission a conclusion can be drawn :

- the main source of information on the leukemia cases is available on the basis of the oblast oncodispensary;
- there are no information losses beginning from 1987;
- the clinical and biological materials are readily accessible;
- There is an agreement with the leaders of the oblast health department on the Project accomplishment in Cherkasy oblast;
- A working group has been formed involving highly qualified people which are interested in the problem, to be engaged in the Project accomplishment on the oblast level;
- the sources of information on the leukemia cases have been studied.

The results of the mission also show that specific features of each oblast involving a member of cases, a number of organizations possessing information to cooperate with will determine the number of people in the working group. A decision on this problem can only made after detailed acquaintance with the situation in each oblast.

Report on Mission to Cherkasy oblast #2.

According to the plan for the Interim Period of the Draft Proposals as to "Case-Control Study of Leukemia among Chornobyl Cleanup Workers in Ukraine" a group of the Program participants from the RCRM.Ac.Med.Sci. of Ukraine involving head of the epidemiologic group Ledoschuk B.A., scientific secretary, hematologist Dyagil I.S., epidemiologist Gudzenko N.A. and dosimetrist Pasalskaya L.F. visited Cherkasy oblast on April, 25, 2000.

The main tasks of the trip were as follows:

1. To evaluate progress in creating Leukemia Registry in Cherkasy oblast as well as quality of the information gained.
2. To analyze problems the local personnel faces while creating Leukemia Registry and ways for their solution.
3. To make a plan for subsequent work to form Leukemia Registry.
4. To select local personnel for accomplishing the Project.

During the reported time the specialists from Cherkasy oncodispensary have made a list of leukemia cases/ related diseases for 1987-1988, i.e. for two full years.

The first was found out to have been made according to the requirements.

For the time being, there are no problems in making the list of cases. The scope of work is Cherkasy oblast is assumed to be extended since some cases may have been treated at the hospital in Uman, Cherkasy oblast. Therefore, the list may be supplemented with the information from this hospital.

According to the estimates by the specialists from the RCRM and local personnel the list of leukemia/related diseases in Cherkasy oblast for 1989-1991 will have been compiled by June, 15, 2000. By this time the next meeting of the RCRM specialists and local personnel is planned.

The main local personnel has been selected in Cherkasy oblast to accomplish tasks as to forming Leukemia Registry. They are as follows:

1. Paramonov V.V. – a supervisor;
2. Pilipenko G.V. – a hematologist.

THE REPORT ON MISSION IN THE CHERNIHIV OBLAST

According to the developed schedule for the interim period of the Project "Proposal for a case-control study of leukemia among Chornobyl clean-up workers in Ukraine" the group of the participants of the Program of the Research Center for Radiation Medicine of AMS of Ukraine including the chief of the epidemiological group B. Ledoschuk, scientific secretary, hematologist I.Dyagil, the chief of the hematological group V.Klymenko, epidemiologist N. Gudzenko and dosimetrist L.Pasalska visited the Chernigiv oblast on April 3, 2000.

The main tasks of the business trip were:

1. To present the offered Draft on the Phase II of a study in the oblast of public health services, regional oncological dispensary, local department of the State Registry;
2. To determine potential sources of the information containing items of information on leukemia cases and related disorders;
3. To select of the responsible persons from local staff to work with the information sources;
4. To acquaint local staff involved in execution of the Project in the Chernihiv oblast with the objectives and the tasks of the work;
5. To select previously local staff for realization of search, tracing and interviewing of cases and controls.

After arrival in Chernihiv the group of the experts from RCRM was accepted by the deputy chief of the oblast public health services in the Chernihiv oblast N.Romanyuk and he was acquainted with the main tasks carried out within the framework of the joint American-Ukrainian contract between National Cancer Institute (USA) and Research Center for Radiation Medicine of AMS of Ukraine with the purpose to study effect of ionizing radiation on the leukemia development. The amount of the work to be carried out by the staff was specified. The representative of the administration of the oblast has supported idea of realization and execution of the Project in the Chernihiv oblast within the framework of the international Program.

Then the meeting was held with the head physician of the dispensary of radiating protection M.Puskov who has told about his institute and what functions it executes. This institute has been functioning since 1994. In 1996 at the dispensary a department was open

for 100 patients including 50 children and 50 adults. Now is there are 80 beds (20 children's beds were reduced). The department for the adults treats all the persons suffered following the Chornobyl accident and living in the territory of the oblast. The department for out-patients at dispensary is estimated for 395 visits per day. At the dispensary a highly skilled hematologist works treating all suffered persons with hematological diseases. The dispensary carries out annual routine physical examination of all categories of the suffered, including clean-up workers. In total there are 160 941 suffers registered in the oblast among them 11 118 clean-up workers . The review panels involved in establishing radiation-related diseases for the clean-up workers living in the Chernihiv oblast is in Kiev at the Institute of oncology.

In the oblast oncological dispensary the head of physician V.Zotov also was acquainted with the tasks facing participants of the Project. He told that oncological dispensary has been functioning since 1986 and has 340 beds including 40 hematological ones. Besides in Pryluki and Nizhyn there are oncological departments for 30 patients each where the patients with hematological diseases can also be treated.

The local Cancer Registry is at the oblast oncological dispensary and contains the information on all leukemia patients since 1994. The database of the Cancer Register contains 20 000 records. The ICD-10 is used.

At the oblast oncological dispensary all possible sources of the information on leukemia cases registered in oblast were defined. They involve records of the reception and hematological departments where all patients are registered as well as archive of medical records. The records of the reception department contain all information on patient including a surname, name and patronymic; date of birth; home address; address of the next-of-kin and their telephones; the diagnoses; dates of arrival and discharge; # of a medical record. It was found out that there are records for all years since 1987 till the present time. Losses are insignificant: there is no information for 3 days in 1990.

The main information concerning of the leukemia patients is at the oblast oncological dispensary. To accomplish the tasks posed the staff including a hematologist and a technician was selected. They were training how to fill in the form on each separate leukemia case. All work will be executed using the paper form and transferred in Kiev. To correct execution of the tasks set this work will be carried out under the supervision of the coordinator from RCRM.

The hematological department (head D.Dvorak) is staffed with qualified personnel and provides diagnostics and treatment of the leukemia patients and lymphoma at the up-to-date level. All clinical information is contained in medical records and out-patient records in archive of the oblast oncological dispensary.

The laboratory service of the dispensary is represented by skilled technicians. The diagnostics is adequate and up-to-date. The biological material is stored in the laboratory archive.

An agreement on the necessity of the teeth collection from clean-up workers for realization EPR dosimetry is made with the head dentist of the oblast.

Thus, as a result of the accomplished business trip it is possible to make the following conclusions:

- The consent of the administrations of the public health services of the oblast for realization of the project in the Chernihiv oblast was obtained;
- The sources of the information on the leukemia cases were studied;
- The basic sources of information on leukemia cases is at the oblast oncological dispensary;
- The clinical material is readily available and the biological material is stored in archive of the laboratory and is available for study;
- The local work group consisting of the skilled and interested specialists is formed to perform the prime tasks of the Project (first of all, creation of the Leukemia Registry).

REPORT ON MISSION TO DNIPROPETROVSK OBLAST

In concordance with the plan developed for the interim period of the Project "A Case-Control Study of Leukemia among Chornobyl Cleap-Up Workers in Ukraine " a group of participants of the program from the Research Center for Radiation Medicine, Academy of Medical Sciences of Ukraine (RCRM, AMSU) including Prof. A.Ye.Romanenko, Director of the Project from the Ukrainian side; Dr. O.Tsvetkova; Prof. B.Ledoschuk, Head of an epidemiological group; Prof. V.Klymenko, Head of a hematological group; Dr. I.Dyagil, Scientific secretary, hematologist; Dr. N.Gudzenko, epidemiologist; Dr. L.Pasalskaya, dosimetrist, have visited the DNIPROPETROVSK oblast on 16-20, May, 2000.

Basic tasks of the mission included:

1. Institution of contacts with managers of medical institutions in the oblast based on which the study will be implemented;

2. To represent the Project proposed on the Phase II of studies in the medical institutions of the oblast: the Oblast Public Health Department, hematological units of oblast (city) hospitals in the cities of DNIPROPETROVSK, Dniprodzerzhinsk, Kriviy Ryh, the oblast oncological dispensary, the oblast unit of the National Registry;

3. To determine potential sources of information containing evidence on cases of leukemia and related diseases;

4. To inform local personnel engaged for implementation of the Project in the DNIPROPETROVSK oblast about goals and tasks of the work;

5. To select local personnel for implementation of the work with information sources;

6. To conduct a working meeting with a dentist responsible for collection of material for EPR-dosimetry in the DNIPROPETROVSK oblast, to analyse progress in his work and problems in material collection.

DNIPROPETROVSK

Public Health Department of the DNIPROPETROVSK Oblast State Administration.

Prof. A.Ye.Romanenko introduced the Study of Leukemia within the framework of Joint American-Ukrainian Agreement between the National Cancer Institute and the Research Center for Radiation Medicine to Dr. V.A.Anissimov, Deputy Chief, Public Health Department, Oblast State Administration. Proposals were positively assessed and promotion was guaranteed in implementation of tasks of the Project.

Oblast Dispensary Unit on Medical Care for Victims of the Chornobyl NPP Accident.

The RCRM specialists were received by Dr. T.I. Chekmareva, manager of the oblast dispensary unit on medical care for victims of the Chornobyl NPP accident. The unit is located in the Mechnikov Oblast Hospital in the city of DNIPROPETROVSK. Dr. T.I.Chekmareva was an interviewer during the Phase I of the Project. The Project Programme and basic tasks of the Project were introduced.

The State Registry is located in that unit where data about all the victims is contained, including clean-up workers. The manager of the unit has established contacts with all the responsible physicians treating clean-up workers on local level. Extracts from medical documents are available for part of leukemia cases registryed in the State Registry. The unit is equipped with highly qualified staff (physicians, an engineer, a medical statistician) and a necessary equipment.

Besides the dispensary number of medical institutions are giving medical aid to participants of elimination of consequences of the Chornobyl NPP accident.

Board of experts on institution of connection of a disease with ionizing irradiation is also functioning based on the Mechnikov Oblast Hospital. Here cases of clean-up workers residing in 4 regions of Ukraine, including the DNIPROPETROVSK oblast are being considered.

City Clinical Hospital No. 4 in DNIPROPETROVSK.

Based on that hospital a hematological unit is located where specialised aid is accomplished for patients residing in the city of DNIPROPETROVSK and the DNIPROPETROVSK oblast. The unit is functioning since 1990. Before the unit was located in the city hospital No. 11. Archives of the hematological unit were transported from the hospital No. 11 to the hospital No. 4.

The unit has 60 beds. Some patients are served at out-patient basis in the consultative out-patient department (polyclinics) of the hospital. Diagnostics and therapy of patients with leukemia is accomplished in the unit.

Sources of information about leukemia cases and relative diseases could be:

- a registry of records of patients treated in the hematological unit;

- a registry of records of patients who came for therapy into the hospital No. 4 (admittance unit);

- archive documents (charts of patients who left the hospital (form No. 66), chart of a patient staying in the hospital etc.)

A registry of records of patients having been treated in the hematological unit (the hematological unit) contains the following columns: number of a case record; date of arrival; surname, name, patronymic; age; place of work and position; who sent him to the hospital; home address; diagnosis; date of leaving the hospital.

Registrys are available for the whole time period studied (1987-2000) excluding the period of October, 1988 - May, 1990.

Data on registration of patients who came to the hospital No. 4 (a admittance unit) are available since 8, June, 1992. Also such data is available: date; time of arrival; number of a case record; surname; name; patronymic; date of birth; home address; place of work, position; who sent him to the hospital; diagnosis upon arrival; a unit.

Data on patients who came to the hospital before 8, June, 1992 is not available. Since 1995 all the data of the admittance unit and also additional information from the hematology unit (definite diagnosis, code of definite diagnosis, date of leaving the hospital, date of death) remain in software outlook in computer files. Codes of diagnoses before 1999 are given in concordance with ICD-9 and beginning from 2000 - in concordance with ICD-10.

A pathology unit is located in that hospital where all the pathological investigations of biopsies and autopsy are accomplished.

Oblast Clinical Oncological Dispensary in the city of DNIPROPETROVSK (DOOD).

Dr. O.I. Balashova, Chief Doctor of the oncological dispensary, was acquainted with tasks of the participants of the Project in the DNIPROPETROVSK oblast. The work planned on the Project was positively assessed and promotion is guaranteed in implementation of tasks of the Programme. Patients with leukemia and related diseases are not treated in the DOOD. Multiple myeloma patients are sent for therapy into the hematological unit of the hospital No. 4.

Based on the oblast oncological dispensary the oblast **Cancer Registry** is functioning managed by Dr. N.N.Shestakova. The Cancer Registry contains data on oncological patients for period studied in the Protocol. Annual verification of data is accomplished together with a State Registration Offices (so called ZAGS) on deceased cases and causes of their deaths. It provided completeness of data.

Hospital for Railway Workers.

Patients with leukemia and related diseases from the DNIPROPETROVSK oblast could be supervised in the hospital for railway workers where some beds are available in a therapeutic unit. This source of information is not basic one, thus it will be studied later.

Besides, an agreement was concluded with Dr. L.V.Zayets, responsible dentist of the oblast, on necessity of teeth collection from participants of elimination of consequences of the Chornobyl NPP accident for accomplishment of EPR-dosimetry.

DNIPRODZERZHINSK

Population of the city is 275 000. Group of the RCRM specialists had a meeting with Dr. V.N.Loginov, Head, the City Public Health Department. He was acquainted with the Protocol of Studies and tasks of local health care authorities. Dr. V.N.Loginov supported idea of fulfilment of the Protocol in the city of Dniprodzerzhinsk and expressed his readiness to promote its implementation.

City Hospital No. 9.

The City Hospital No. 9 headed by Dr. Yu.G.Kikot, Chief Doctor, has 500 beds. There is a hematological unit for 30 beds where diagnostics and therapy of leukemia and related diseases is accomplished for residents of the city of Dniprodzerzhinsk and several adjascent districts.

The unit is equipped with qualified staff.

Information sources on patients with leukemia and related diseases could be:

- a registry of records of patients treated in the hematological unit;

- a registry of records of patients who came for ttreatment into the hospital No. 9 (a admittance unit);

The registry of the hematological unit contains the following information:

ID number; date of admittance; surname, first name, patronymic; year of birth; address; place of work; a medical institution having sent a patient into the unit; diagnosis upon arrival; definite diagnosis; date of discharge; disease outcome.

Data was not available for the following years: 1987, 1988, 1990, 1991, 1992.

A registry in the admittance unit contains such data: ID number; date of admittance; surname, first name, patronymic; date of birth; address; a medical institution having sent a patient into a unit; a unit; ID number of a case record; diagnosis on admittance.

Registrys are available for the whole period studied excluding the period from 16, April, 1997 till 13, May, 1997.

KRIVIY RYH

The group of specialists was received by Dr. A.V.Lukyanov, Deputy Head, Public Health Department of the city of Kriviy Ryh. He was acquainted with the Protocol of Studies and tasks of local health care authorities. Dr.A.V.Lukyanov supported the idea of fulfilment of the Protocol in the city of Kriviy Ryh and expressed his readiness to promote its implementation.

Hospital No. 5.

RCRM team had a meeting with managerial staff of the hospital (Dr. L.G.Miryanova, Deputy Chief Doctor) and presented the Protocol and its tasks.

The hospital is designed for 500 beds, including 40 hematological ones. The unit is located in a separate three-storey building. Here diagnostics and therapy is accomplished for patients with leukemia and related diseases from the city of Kriviy Ryh and 5 adjascent districts (rayons).

Sources of information on patients with leukemia and related diseases could be:

- a registry of records of patients treated in the hematological unit;
- a registry of records of patients treated in the hospital No. 9 (a admittance unit);

The registry of the hematological unit contains the following data: ID number; date of admittance; number of a medical record; surname, first name, patronymic; age; a medical institution having sent a patient into the unit; home address; place of work; diagnosis upon admittance; definite diagnosis; date of discharge; disease outcome. There is no any loss of information for the period studied.

The registry of the admittance unit contains such data: ID number; date of admittance; surname, first name, patronymic; age; address; a medical institution having sent a patient into a unit; a unit; number of a medical record; diagnosis upon admittance. Registries are avilable for the whole period studied.

Hospital No. 3.

Representatives of the RCRM were received by Dr. B.A.Zabelov, Chief Doctor of the Hospital. The Project and its basic tasks were introduced.

The hospital serves for victims of the Chornobyl NPP accident residing in the city and the district. About 4 000 clean-up workers are registryed there. An affiliate of the oblast unit of the State Registry is located at the hospital. Additional information is being accumulated about each a patient with an oncological disease.

Local personnel

Taking into account tasks of the Project which should be fulfilled on local level selection of personnel was accomplished for work on institution of a Leukemia Registry.

These are:

1. Supervisor - Dr. T.I.Chekmareva - manager of a dispensary unit on medical aid for victims of the Chernobyl NPP accident in the Mechnikov Hospital (city of DNIPROPETROVSK).

2. Hematologist - Dr. P.E.Kaplan - manager of a hematological unit in the hospital No. 4 in DNIPROPETROVSK.

3. Hematologist - Dr. V.F.Dregval - city of Kriviy Ryh.

4. Technician - T.I.Ovsyannikova - nurse;

5. Technician - O.A.Khrapko - nurse;

6. Technician - Dr. L.V.Lozinsky - city of Dniprodzerzhinsk.

The manager of a hematological unit of the hospital No. 4 in DNIPROPETROVSK was selected for accomplishment of works on establishment of the Leukemia Registry, because she posesses basic amount of information on cases of diseases studied. Besides, Dr. P.E.Kaplan has wide professional links with all the medical institutions in the oblast where patients with leukemia and related diseases could be treated, and also with the Oblast Cancer Registry. Thanks to this fact Dr. P.E.Kaplan can provide completeness of data for the Leukemia Registry for the DNIPROPETROVSK oblast.

Thus, the following **conclusions** could be made on results of the mission:

- contacts have been established with managers of medical institutions in the oblast on basis of which the study will be accomplished;
- institutions of the DNIPROPETROVSK oblast (cities of DNIPROPETROVSK, Dniprodzerzhinsk, Kriviy Ryh) have been studied which could have necessary information on leukemia cases;
- basic sources of information about leukemia patients are kept in hematological units of the hospital No. 4 in DNIPROPETROVSK, the hospital No. 9 in Dniprodzerzhinsk, the hospital No. 4 in Kriviy Ryh and the Oblast Cancer Registry;
- additional information about leukemia cases could be obtained from the Hospital of Railway Workers;
- the oblast unit of the State Registry and the specialized board of experts at Counsil for establishment of the relationship between disease and radiation exposure wiil be used both for formation of the Leukemia Registry and subsequent work on search, establishment of contacts and interview of cases/controls and their "proxies";
- clinical material from all the institutions is easily available, biological material is kept in archives of laboratories and is available for the study;

- a local working group has been formed for implementation of first rank tasks of the Project (formation of the Leukemia Registry) consisting of highly qualified specialists;
- work on material collection for accomplishment of EPR-dosimetry should be intensified.

Report on mission to Kharkiv oblast

According to the plan developed for the Interim period of the draft Proposals as to "Case – Control Study of Leukemia among Chornobyl Cleanup Workers in Ukraine" a group of the Program participants from the RCRM, Ac.Med.Sci. of Ukraine including a leader of the epidemiologic group Ledoshchuk B.A., a leader of the hematological group Klymenko V.I., scientific secretary, hematologist Dyagil I.S. and epidemiologist Gudzenko N.A. visited Kharkiv oblast on April, 18-19, 2000.

The **main tasks** of the business trip were as follows:

1. To establish contacts with the leaders of the medical institutions of the oblast on the basis of which a study will be carried out;

2. To present the proposed draft on the Phase II of the study in the medical institutions of the oblast;

3. To determine potential sources of the information containing data on the leukemia cases and related diseases;

4. To acquaint the local personnel involved in performing the Project in Kharkiv oblast with the aims and tasks of the work;

5. To select local personnel to carry out work with the information sources.

The oblast specialized dispensary for radiation protection of the population

The specialists from RCRM were received by the head physician of the oblast dispensary for radiation protection of the population Vovk A.D. He was acquainted with the main tasks of the work carried out within the framework of the joint American-Ukrainian agreement between the National Cancer Institute of the USA and RCRM, Ac.Med.Sci. of Ukraine to study effect of the ionizing radiation on developing leukemia. The chief physician characterized the institution.

All categories of the sufferers involving clean-up workers are examined in the dispensary. On its basis the oblast department of the State Registry is functioning. 22,500 people are registered there, among them being 16,600 clean-up workers. 5,456 of them are residents of Kharkiv city. 2,000 people have dose exposure above 25 Gy. Besides the dispensary, a number of medical institutions of the city render specialized aid to the clean-up workers.

In the dispensary polyclinics the hematologist's consultation is available, if necessary. The hematological patients are treated in the specialized department of the oncological dispensary.

A specialized expert council for establishing relationship between a disease and ionizing radiation effect functions on the basis of the dispensary for radiation protection of the population. The cases from three oblasts of Ukraine namely, Kharkiv, Sumy and Poltava are considered there.

Kharkiv oblast clinical oncological dispensary.

The deputy head physician of the oncological dispensary was acquainted with the tasks facing the participants of the Project in the oblast.

The deputy head physician of the dispensary Nechvidova Ye.A. characterized the institution. The dispensary has been functioning since 1947, it has 540 beds. The dispensary involves hematological department (60 beds) where the patients involving clean-up workers from Kharkiv oblast are diagnosed and treated. Highly qualified hematologists who mastered the up-to-date methods of leukemia and lymphoma diagnostics and treatment work in the hematological department.

The information sources for the leukemia Registry formation are as follows:

1. The registration records of the casualty ward at the department. An individual entry in the record involves family name, name, patronymic; age; job; dates of his stay in the department; No. of the medical record; diagnosis while discharging from the department; address and telephone of the next-of-kin. The records are available for the whole period under study.

2. Records on those died of leukemia are made by the employee of the department according to the data of the oblast statistical bureau . The records have been regularly made since 1995.

The proposed candidate to fulfill the work at the oblast level was talked to. The whole work is assumed to be fulfilled on the paper carrier and transferred to Kyiv. The work will be supervised by the coordinator from RCRM.

The medical records for all hematological patients are stored in the archive of the oncodispensary.

The staff of the laboratories are highly qualified. The diagnostic techniques are adequate and up-to-date. The biological material is stored in the archive of the laboratory.

Cancer Registry.

Cancer Registry functions on the basis of the oncological dispensary.

Hospital for the railway transport workers.

The patients with the hemopoietic system diseases in Kharkiv oblast may be treated in the hospital for the railway transport workers where there are 5 beds in the rheumatological department. The data on these patients are not available in the hematological department of the oncological dispensary.

The Kharkiv Institute for Medical Radiology.

Besides the institutions above, the diagnostics and treatment of the patients is also carried out at the Institute for Medical Radiology. The specialists from RCRM were received by the deputy director of the Institute Mitryayeva N.A. and the head physician Vasilyev L.Ya. The hematological patients are examined and treated in several departments, mainly in the department for radiation pathology. All up-to-date methods of diagnostics and treatment are used.

The information sources to form the leukemia Registry are as follows:

- registration records of all the patients in the casualty ward. An individual entry involves the following data: No., date of entering the hospital, family name, name and patronymic, age, job, department, diagnosis, home address, date of discharge from the hospital. It was found out that all registration records are available, there are no losses.

- the records of the patients from the category of the sufferers including clean-up workers (individual entry contains the same data).

- data base for the persons having been examined in the clinics since 1993. An individual entry for 1993-1995 contains the following data: family name, initials, dates of staying in the clinics. Individual entry since 1996 involves family name, name , patronymic, date of birth, dates of his stay in the clinics, diagnosis according to ICD-9, No. of the medical record, special therapy used, number of hospitalizations in the current year.

Besides, an agreement was achieved with the head stomatologist of the oblast as to the necessity to collect teeth from the clean-up workers to carry out EPR dosimetry.

Thus, as a result of the business trip the conclusions may be made as follows:

- a contact has been established with the authorities of the medical institutions of the oblast on the basis of which the study will be conducted;

- the institutions of Kharkiv city were determined which may contain the necessary information on the leukemia cases;

- the main source of information on the leukemia cases was found out to be on the basis of the oblast oncodispensary;

- additional information as to the leukemia cases may be received from the Institute for Medical Radiology and hospital for the railway transport workers;

- the oblast department of the State Registry and specialized expert council as to establishing relationship between a disease and effect of the ionizing radiation will be used both to form the leukemia Registry and for subsequent work to search, establish contacts and interviewing cases/controls and their proxies;

- the clinical material in all institutions is readily accessible, biological material is stored in the archives of the laboratories and is accessible for study;

- a local working group consisting of the highly qualified specialists has been formed to accomplish the paramount tasks of the Project, i.e. forming the leukemia Registry.

REPORT ON KYIV CITY

According to the schedule for the Interim period of the Project "Case-Control Study of Leukemia among Chornobyl Clean-up Workers in Ukraine" a group of the Project participants from the Research Center for Radiation Medicine, Ac.Med.Sci. of Ukraine involving chief of the epidemiologic group B.A.Ledoshchuk, chief of the hematological group V.I.Klimenko, scientific secretary, hematologist I.S.Dyagil and epidemiologist N.A.Gudzenko visited a number of the medical institutions in Kyiv.

The main tasks of the visits were as follows:

1. To establish contact with the supervisors of the medical institutions of the city to be involved in the study.
2. To present the proposed Project on Phase II of the study at the medical institutions of the city.
3. To specify potential sources of information containing data on the cases of leukemia and related diseases available at different institutions in Kyiv
4. To choose local personnel for work with the information sources.

On April, 19, 2000 the Central departmental Council for establishing disease relationship with the Chornobyl accident was visited. The Council is located in the laboratory building of the RCRM (Pushcha Voditsa, 30, Lesnaya Str.); it has an orderly arranged archive. The Council has been functioning since 1990 and numbers about 10,000 cases. The data on all cases of leukemia and related diseases were found out to be contained both on the paper media (arranged in special files) and on the electronic files. The Council considers cases of all persons suffered following the Chornobyl accident and of those forwarded from the other expert councils.

Each file contains all detailed extracts from the medical records, extracts from the out-patient records , dosimetric data and all passport data. Preferably the cases from Kyiv city and Kyiv oblast are considered. The information involves family name, name, patronymic, date of birth, job before and after the accident, home address, data on the character of one's service in the 30-km zone, dose exposure, final diagnosis, all laboratory tests including blood tests, myelogram, threpanobiopsy, lymph node biopsy as well as autopsy data.

Kyiv city hospital No.9.

On March, 30, 2000 a visit was paid to the city hospital No.9 which involves two hematological departments for 60 and 35 beds. They are clinical bases of the Research

Institute for Hematology and Transfusiology, Ministry of Health of Ukraine. Residents of Kyiv city as well as of other regions of Ukraine are treated at these departments.

The first department (for 60 beds) has been functioning since 1973, the other (for 35 beds) – since 1992.

Of note, in1996 the first patients suffered from the Chornobyl accident were treated at the department of the radiation pathology at this hospital.

The registration documents presented for the study:

Registers of the reception ward of the hospital are available from 1987 to 2000. They involve the following data:

- Ordinal number;
- Date and time of admittance;
- Family name, name and patronymic (full);
- Age at the moment of reception (beginning from Sept.,16, 1993 –year of birth);
- Address (city, district, street, building, apartment);
- The institution that forwarded the patient;
- Department of hospitalization;
- No. of the medical record;
- Diagnosis of the institution that forwarded the patient.

Statistical coupons are transferred monthly to the archive and are arranged according to the departments and years. However, the terms of their storage do not exceed 5 years therefore, the feasibility of their study for the whole period from 1987 is rather problematic. The responsible persons for the statistical coupons are employees of the office for registration and medical statistics.

The archive contains medical records and in case of their withdrawal due to some causes e.g. judicial claims, etc., there is the corresponding information on their extradition.

Hematological department No.1 for 60 beds.

Medical registers of the patients' treatment from Nov.,14,1991 to March, 17 1997 and from March,18, 1997 to March,31, 2000 were presented. The registers are laced and numbered. They involve the following information:

- No. of the medical record;
- Date of reception;
- Age (number of years);
- Family name, name, patronymic (full);

- Diagnosis on reception;
- The institution that forwarded the patient;
- Home address;
- Diagnosis on discharging;
- Date of discharge;
- Duration of treatment at the in-patient department.

During 1999 about 600 patients were treated at the department, some of them – repeatedly. While examining the registers we encountered problems related with decoding of some entries of the registers especially in case of cuttings of the diagnoses, abbreviations and etc. It suggests the necessity of hematologist's participation while making the list of the diseased.

The test timing made while filling out the chart copied from the registers indicated 28 min. 30 sec spent on average to extract information for each case, or 24 charts per hour while working continuously.

Hematologic department No.2 for 35 beds started functioning from July, 8, 1992.

The medical records have not been withdrawn from the department and have not been transferred to anybody.

Statistical coupons are transferred to the archive every month and for the deceased they are stored separately.

Medical registers of the patients treatment were presented for the period from Nov., 14, 1992 up to now. The terms of their storage are not specified and the data presented in the registers may be incomplete.

In the laboratory of the department special hematological studies are carried out involving blood tests, bone marrow puncture, threpanobiopsy. The preparations of the threpanobiopsy are stored in the pathology department. The smears of the bone marrow are stored for the recent 2-3 years in the laboratory archive.

Cytochemical studies and immunophenotyping are carried out at Kavetsky oncological Institute and are stored there.

Central Military Hospital of Ukraine.

The hospital is a versatile medical institution for 11,100 beds. The hematological department has 20 beds. Military men of the Ukrainian army, officers in reserve and members of their families are treated at this department. The hematological department opened in 1992.

Prior to this period there were 10 hematological beds at the cardiological and then therapeutical departments. There are registers of patients' hospitalization in 1990,1991 and from November, 1992 up to now. The registers contain the following information:

ordinal number, date of reception, No. of the medical record, family name, name, patronymic, age, military rank and unit, preliminary and definite diagnosis, date of discharge, outcome, the number of the days spent at the department.

In the laboratory of the hospital they accomplish al diagnostic studies involving tests of peripheral blood, of bone marrow, of the lymph nodes. The preparations are only stored for the recent 3 years. Threpanobioptats and autopsy materials are examined and stored in the pathology department of the hospital.

The Research Center for Radiation Medicine, Ac.Med.Sci. of Ukraine.

A versatile clinics of the RCRM involves hematological department where the patients suffered as a result of the Chernobyl accident are treated including clean-up workers from Kyiv city and all oblasts of Ukraine. There is a reception ward at the hospital where all patients to be examined and treated are received. The register available from 1987 contains the following information: ordinal number and No. of the medical record; family name, name and patronymic; age; home address; job; preliminary diagnosis and date of reception.

The hematological department opened in 1987 for 20 beds and since 1999 – for 30 beds. All patients with leukemia, related diseases and malignant lymphoma are diagnosed and treated at this department. There is a register of all patients involving the following information: ordinal number and No. of the medical record; family name, name and patronymic; age; home address; job; preliminary and definite diagnosis, number of receptions to the department; date of reception and of discharge; number of the in-patient days and outcome.

The hematological department is staffed with highly qualified personnel.

The laboratory is available at the department to render service for both in-patients and out-patients. Here special hematological studies are carried out including tests of the peripheral blood, of bone marrow, of threpanobioptats.

Kyiv regional expert council for establishing causative disease relationship with the Chornobyl accident factors.

The council has been functioning since 1991 and accepts documents from the sufferers of Kyiv, Chernigiv and Cherkasy oblasts.

Information on all leukemia cases and related diseases is contained both on the paper media (arranged as a special file) and on the electronic file.

The information involves all detailed extracts from medical record, from the out-patient records, dosimetric data and all passport data including family name, name, patronymic, date of birth, job before and after the accident, home address, details of the work performed during one's service in the 30-km zone, dose exposure, final diagnosis, laboratory studies involving blood test, myelogram, threpanobiopsy, lymph node biopsy and autopsy data.

Thus, as a result of the business trip the conclusions may be made as follows:

- a contact has been established with the supervisors of the city medical institutions on the basis of which a study will be carried out;
- the institutions of Kyiv city has been inspected which may contain the necessary information on the leukemia cases;
- the clinical material at all medical institutions was found out to be readily accessible for a period of 14-15 year;, the biological material stored in the archives of the laboratories is available for the recent 1-3 years and is accessible for the study;
- a local working group consisting of the highly qualified and interested specialists has been formed to accomplish primary tasks of the Project – Leukemia Registry creation.

DRAFT

APPENDIX 2.

OPERATIONAL MANUAL FOR THE PROJECT "A Case-Control Study of Leukemia among Chornobyl Clean-Up Workers in Ukraine"

CONTENT

1. Introduction to the Study.
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Draft

Appendix 3.

Academy of Medical Sciences
of Ukraine

National Cancer
Institute, USA

Research Center for
Radiation Medicine,
Ac. Med. Sci. of Ukraine

Project

"Case-Control Study of Leukemia among Chornobyl Clean-up Workers in Ukraine"

INSTRUCTION

to form the Leukemia Registry

Kyiv – 2000

The Instruction was compiled:

by supervisors and staff of the epidemiologic and hematologic groups of the Project "Case-Control Study of Leukemias Among the Clean-up Workers Following the Chernobyl Accident in Ukraine":

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It is intended for the staff of the medical institutions of Dnipropetrovsk, Kyiv, Cherkasy, Chernihiv oblasts and Kyiv city taking part in collection of the primary information on the cases of leukemia, multiple myeloma, myelodysplastic syndrome and related diseases.

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" " _____ 2000

I.Objective:

Search, selection and registration of the cases of leukemia and related diseases among the males aged 18-60 years – residents of Dnipropetrovsk, Kyiv, Kharkiv, Cherkasy, Chernihiv oblasts and Kyiv city during the period of Jan., 1, 1987 – Jan., 1, 2001 to create databases of the Leukemia Registry.

II.Subject of the study:

Registered cases of leukemia, related diseases as well as syndromes, unspecified states in the patients above.

III.Sources of information:

- Register of the patients' admittance (Y 001/y);
- Register of the patients an the hematological department;
- Statistical coupon (form No. 66);
- Form of the discharged patient (form No. 286);
- Medical record of the in-patients (form No. 007);
- Form of the out-patients (form No. 025).
- Other medical documents (pathologist's conclusion, records of the expert councils, of the Medical-Labor Expert Commission, the Review panels involved in establishing radiation-related diseases, etc.

IV.Technology for information acquiring

1. Reference data involving organization, institution, participants and executors of the Project (Appendix 3.1), information on location and full name of the medical-prophylactic institution (organization).

2. Family name, name, patronymic, office telephone and fax of the supervisor of the institution and responsible persons for collection of the epidemiological and hematological information.

3.. General characteristics of the oblast, city and medical-prophylactic institution (demographic data on the population number; structure and capacity of the institution, structure of the pathology registered) – Appendix 3.2.

4. Study of the scope and completeness of the sources of information (by years) – Appendix 3.3.

5. Study of the scope and completeness of the diagnostic and biological material – Appendix 3.4.

6. Data collection form (DCF)from the medical registers and reports above – Appendix 3.5.

7. Preparation and presentation of the report according to the Approval document - Appendix 3.6.

V. Data collection form (DCF)

Data for each case of leukemia or related diseases are filled out in the "Data collection form" (DCF)– Appendix 3.5. Data on each separate case are obtained from one of the information sources above.

VI. Instructions as to filling out the Data collection form

General rules (for filling out all columns of DCF)

The form is filled out by specially trained persons from medical staff of the medical-prophylactic institutions. The persons filling out the form are personally responsible for accuracy in copying out information from the documents above.

The columns in the chart are filled out with ball (gel) pen in printed letters without mistakes, in original language.

4 types of data registration are anticipated while filling out the form:

- Using the digit codes;
- Without digit codes;
- Encircle the necessary data in the right corner of the line;
- Underline one of the variants given.

While filling out the columns checked only one digit or letter is written in each box.

While indicating dates of birth, admittance in the department and discharge – two digits are written in the each box – (dd) for day, (mm) for month, (yy) for year (the last 2 from 4 digits) e.g., 04 01 97 means January, 4, 1997).

While registering date of death four boxes are anticipated to indicate year (yyyy), i.e. year is indicated fully. E.g. 1997 means year 1997.

In case of uncertain for interpretation data given in the initial statistical forms, e.g. illegible writing, in front of the ordinal number a note of interrogation is placed in the left corner of the sheet before the column. Further upon making the controversial point more accurate this note is crossed out.

Particular instructions as to filling out specific columns of the DCF.

Inscription below the title of the form.

The first line – *name of the institution.* Give an official name of the medical institution where the form is filled out, followed by the ordinal number of the medical subdivision. E.g. hematological department No.1 or No.2.

The second line is filled out by:

Underlining the source of the data in the form (register of admittance in hospital or hematological department, statistical coupon (form No. 66) or other documents.

Filling out the columns of the DCF.

The first column – *"No. of the medical record"* and *"Status of a clean-up worker"* is filled out as follows:

- the symbol No. is followed by a digital marking of the medical document adopted at the given medical institution;
- one of the digital designations of the status of clean-up worker is underlined: 1- if the status is confirmed; 2 – if it is not confirmed and 3 – if no official information is available as to belonging to the clean-up workers.

The 2nd and 4th columns - "*Family name, name, patronymic*" are filled out in printed letters – one letter in each box without abbreviations.

The 5th line - "*Date of birth*" involves information on the data of birth (day, month, year) and "*age*" (number of full years). The corresponding information being available, both data are given (data and age).

To fill out the column "*age*" it is necessary to use the age classifier.

Age classifier

Years from 1986 to 2001	Age range (number of full years)
1986	18 – 60
1987	19 – 61
1988	20 – 62
1989	21 – 63
1990	22 – 64
1991	23 – 65
1992	24 - 66
1993	25 – 67
1994	26 – 68
1995	27 – 69
1996	28 – 70
1997	29 – 71
1998	30 – 72
1999	31 – 73
2000	32 – 74
2001	33 – 75

While filling out the 6th column - "*address, oblast code*" it is necessary to encircle one of the 6 variants of the two-digit codes corresponding to the particular oblast of the patient's residence according to the classifier below:

Oblast classifier

Oblast(city)code	Oblast (city)
04	Dnipropetrovsk
10	Kyiv
20	Kharkiv
23	Cherkasy
25	Chernihiv
26	Kyiv city

While filling out the 7th column – "*district*" and "*settlement*" name and code of the district is given first, followed by name and code of the settlement. One of the variants (*c – city; v – village; s – settlement*) is underlined.

While filling out the 8th column it is necessary to underline one of the variants *(street, avenue, boulevard, embankment, blind alley, lane, square)*.

While filling out the 9th column No. of the building is given in the empty right part of the line; and No. of the apartment – in the 4–square field, each digit being written in a separate box.

While filling out the 10th and 13-th columns *(date of admittance and date of discharge,* respectively) it is necessary to indicate day *(dd – two digits)*. E.g.. January, 1 1968 – 01. 01. 68.

While filling out the 14th column – *(date of death)* a year is written fully – all 4 digits, one in each box. E.g. January, 1, 1968 is written as follows: 01. 01. 1968.

While filling out the column "*diagnosis on admittance*" and "*on discharge*" (11th and 12th columns, respectively) the code is written using the classifier below – diagnosis, syndrome, and/or symptom; uncertain state.

Working Classifier of Diagnoses

No	Disease code	Disease
I. Acute leukemia	1.1.	Myeloblastic leukemia
	1.2.	Promyelocytic leukemia
	1.3.	Myelomonocytic leukemia
	1.4.	Monocytiv leukemia
	1.5.	Acute erythromyelosis
	1.6.	Acute megacaryoblastic leukemia
	1.7.	Unclassified leukemia
	1.8.	Lowprocentage leukemia (oligoblastic)
II. Chronic leukemia	2.1.	Chronic lymphocytic leukemia
	2.2.	Chronic myelogenous leukemia (blastic cryses)
	2.3.	Osteomyelofibrosis (subleukemias myelosis)
	2.4.	Policytemia vera (erythremia)
	2.5.	Myeloma (Multiple myeloma)
	2.6.	Chronic erythromyelosis
	2.7.	Plasmoblastic leukemia
	2.8.	Hairycell leukemia
	2.9.	Waldestrem disease
III. Myelodisplastic syndrome (MDS)	3.1.	Refractory anemia
	3.2.	Refractory anemia with sideroblast rings

	3.3.	Refractory anemia with excess blast
	3.4.	Refractory anemia with excess blast in transformation
	3.5.	Chronic myelomonocytic leukemia
	3.6.	Недифференцируемый Unclassified (MDS)
IV. Anemia	4.1.	Hypo-, hyper-, aplastic anemia
	4.2.	Unknown anemia
	4.3.	Partial redcell aplasia
V.Others diseases	5.1.	Agranulocytosis
	5.2.	Nonhodgkin lymphoma (lymphosarkoma)
	5.3.	Leukemoid reaktions of different type (myeloid, lymphoid)
	5.4.	Leukopenia
	5.5.	Leukocytosis
	5.6.	Идиопатическая тромбоцитопеническая Idiopathic purpure (Verlhofe disease)
	5.7.	Thrombocytosis
	5.8.	Reticulohystiocytosis
	5.9.	Mononucleosis
	5.10.	Геморрагический синдром
	5.11.	Lymphadenitis (lymphoadenopatia)
	5.12.	Cytopenia or pancytopenia
	5.13.	Aleukemic leukemia
	5.14.	In-patient treatment
	5.15.	Examination at the hematological department

While filling out the **last line at the bottom of the form** it is necessary to indicate:

- family name, name and patronymic (fully);
- date of filling out the form – (dd) – day, (mm) – month, (yyyy) – year. E.g. Stasova Polina Sergeevna – 01. 01. 2000.

VII. Reports of the Executors:

The person responsible for copying out the "Data collection form" presents a weekly report to the responsible executors in the oblast as to the work according to the form of the Approval document - Appendix 3.6 indicating date of the form filling out in the departments and medical institutions.

The responsible executor in the oblast presents a monthly report to the project curator in the oblast.

The curator of the oblast delivers data to the supervisor of the epidemiologic group register and checking up (jointly with the supervisor of the hematologic group of the Project) accuracy of the data and forwards them for the database input.

Appendix 3.2

General Characteristics of the Oblast (City) and Medical Institution

Oblast (city):

_____

Total number of population (as of Jan., 1, 2000)_____ _____

Involving males _____

Out of them males aged 18 – 60 _____

The number of diseases of the hemopoietic and lymphoid system first registered (as of Jan., 1, 2000) _____involving

lymphoma _____ leukemia_____

Institution_____

Department_____

_

	The number of beds		In-patients	
	In the institution	**In the department**	**In the institution**	**In the department**
1987				
1988				
1989				
1990				
1991				
1992				
1993				
1994				
1995				
1996				
1997				
1998				
1999				
2000				

Note:
In case of the several departments at the institution to be studied the number of the columns increases accordingly.

Appendix 3.1

REFERENCE BOOK

Of the organizations, institutions

Postal index _____ _____ Oblast_____
city _____ rayon
_____
str_____,
house_____
Name of the health service organization (oblast, city level)
_____department
head (deputy) Family name,name,patronymic_____
office tel._____
responsible authorities from administration
Family name,name,patronymic
_____
Name of medical-prophylactic institution_____
Address_____
Transport route_____
tel (city code)_____ Fax (_____) _____
E-
mail:_____
Head of the institution_____ _____
_____ office tel
____._____
Deputy head of the institution _____ office tel _____
Head of the organization and methodical study_____ office tel.
_____
Doctor-statistician _____ _____ office
tel._____
Statistician _____ _____ office tel_____
Head of hematological department _____office tel_____
Hematologist_____ _office
tel_____
Chief nurse of the hemat.departm._____
_____
head of the admittance unit _____ office
tel___._____
physician of the admittance unit_____ office
tel___._____
nurse of the admittance unit_____
Stomatological institution _____Address_____
Head of the institution_____office tel__._____
Responsible for biomaterial collection (family name, name,
patronymic)_____
Office tel_____
Nurse_____
_
Note:

Appendix 3.3

Characteristics of the sources of information

_____

oblast,city

_____

institution

	Departments where documents stored	Depth of search of the primary documents (for the period from_____ to_____)				
		Register of the admittance unit	Register of the department	Stastical coupon f-25y	Form of the discharge	Medical record of in-patient
1	2	3	4	5	6	7
1	Department _____	Available From_____ To_____ Not available From_____ to_____	Available From_____ To_____ Not available From_____ to_____	Available From____ To_____ Not available From____ to_____	Available From_____ To_____ Not available From_____ _ to_____	Available From_____ To_____ Not available From_____ to_____

Appendix 3. 4

Characteristics of the sources of the diagnostic and biological materials

_____

oblast,city

_____

institution

	Departments where the materials are stored	Depth of search of biomaterials (for the period from_____ to_____)				
		Bone marrow smears	**Lymph nodes touch**	**Threpano bioptates**	**Histological blocks**	**Autopsy materials**
1	2	3	4	5	6	7
1 2	Department _____ _____	Available From_____ To_____ Not available From_____ to_____	Available From_____ To_____ Not available From_____ to_____	Available From_____ To_____ Not available From_____ to_____	Available From_____ To_____ Not available From_____ to_____	Available From_____ To_____ Not available From_____ to_____

13.	Date of discharge (dd/mm/yy)									
14.	Date of death (dd/mm/yyyy)									

Form fill in _____ Date
_____/_____/_____ y.

Data collection form (DCF) **Appendix 3. 5**

Institution_____

Source of data: register of admittance unit № _____, register of hematol.departm. №_____

f. 66, others (underline)

1.	№ medical record		1.1 Status of clean-up worker (1-yes, 2- no ,3-unknown)
2.	Family name		
3.	Name		
4.	Patronymic		
5.	Date of birth (dd/mm/yy)		5.1Age
6.	Address: oblast (encirclethe oblast code)	04 10 20 23 25 26	
7.	Rayon		7.1Settlement (c., v., s)
8.	Street, avenue, boulevard, square, lane (underline)		
9.	Building		9.1Apt.
10.	Date of admittance (dd/mm/yy)		
11.	Diagnosis on admittance		
12.	Diagnosis on discharge		
13.	Date of discharge (dd/mm/yy)		
14.	Date of death (dd/mm/yyyy)		

1.	№ medical record		1. 1.1 Status of clean-up worker (1-yes, 2- no ,3-unknown)
2.	Family name		
3.	Name		
4.	Patronymic		
5.	Date of birth (dd/mm/yy)		5.1 Age
6.	Address: oblast (encirclethe oblast code)	04 10 20 23 25 26	
7.	Rayon		7. 1Settlement (c., v., s)
8.	Street, avenue, boulevard, square, lane (underline)		
9.	Building		9.1apt.
10.	Date of admittance (dd/mm/yy)		
11.	Diagnosis on admittance		
12.	Diagnosis on discharge		

Состав УЛПА МВД

№	Наименование области	Всего	в том числе с дозами	%	из них 86г.
1	Днепропетровская	1229	1177	95,77	459
2	Киевская	2928	2874	98,16	2459
3	Харьковская	1087	885	81,42	461
4	Черкаская	901	757	84,02	483
5	Черниговская	305	300	98,36	101
6	Киев	3529	2947	83,51	2563
Итого:		9979	8940	89,59	6526